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Effects of continuous intravenous magnesium on features of central sensitisation in complex regional pain syndrome type one patients

Submission date 02/05/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/05/2007	**Overall study status** Completed	
Last Edited 09/05/2019	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effects of continuous intravenous magnesium on features of central sensitisation in complex regional pain syndrome type one patients

Study objectives
Magnesium sulphate reduces pain for more than 50% on the Box scale when compared to the baseline, and for more than two points to the placebo group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Medical Ethical Review Committee of the VU University Medical Center on the 26th February 2007 (ref: 2004/153).

Study design
Randomised, double blinded, placebo controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Complex Regional Pain Syndrome type 1 (CRPS I)

Interventions
Intervention: 70 mg/kg magnesium sulphate continuously administered in four hours via an intravenous infusion (in two 50 ml syringe) of 24 ml/hour a day for a period of five days
Control: an equal amount of NaCl 0.9% solution (in two 50 ml syringe) continuously in four hours via an intravenous infusion of 24 ml/hour a day for a period of five days

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Magnesium sulphate

Primary outcome measure
Pain will be measured in a pain diary at baseline, 1, 3, 6 and 12 weeks after treatment. In this diary patients will record their pain rate on a 11 point Box scale three times daily for a period of one week before each measurement point.

Secondary outcome measures
1. Sensory complaints:
a. McGill pain questionnaire will be used to obtain information about the type of pain experienced by patients
b. Semmes Weinstein Monofilaments will be used to objectively measure sensitivity of the skin (e.g. hypesthesia, hyperesthesia and allodynia)
2. Impairments: patients functional status will be assessed with the Impairment Level Sumscore, in which: pain (measured by Box scale and McGill pain questionnaire), temperature (measured with infrared thermometer), volume (measured with water displacement volumeter) and active range of motion (measured with goniometers) will be converted into a compound sumscore
3. Functional disability: the Radboud Skills Questionnaire, the Walking Stairs Questionnaire and Questionnaire Rising and Sitting Down will be used to assess disability in patients with respectively upper and lower CRPS1
4. Quality of life: The 36-item Short Form (SF-36) and European Quality of Life (EuroQol) questionnaires will be used to measure quality of life

Secondary outcomes will be measured at baseline, 1, 3, 6 and 12 weeks after treatment.

Overall study start date
01/12/2006

Completion date
01/07/2008

Eligibility

Key inclusion criteria
1. Diagnostic criteria for Complex Regional Pain Syndrome type one (CRPS1) according to the International Association for the Study of Pain (IASP):
a. presence of an initiating noxious event or cause for immobilisation
b. continuing pain, allodynia or hyperalgesia, with which the pain is disproportioned to any inciting event and is not limited to the area of an individual peripheral nerve
c. evidence at any time of oedema. Skin blood flow abnormality, or abnormal sudomotor activity in the painful area since the inciting event
d. conditions which could otherwise account for the level of pain and dysfunction should be excluded
Note: criteria b-d have to be met
2. A Visual Analogue Scale (VAS)-spontaneous pain score of 5 cm or higher
3. Patients should be between 18 to 70 years old
4. CRPS1 in one extremity
5. First time experience of patient with CRPS1
6. Other medication has to be stopped for more then one week before the trial starts
7. Patients should give written informed consent

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
72

Total final enrolment
56

Key exclusion criteria
1. Not being able to give informed consent
2. Another (second) chronic pain syndrome, interfering with pain ratings
3. Another syndrome interfering with functional tests
4. CRPS1 in both hands or feet
5. Patient has experienced CRPS1 before
6. Known kidney and/or severe liver disease
7. Known nerve damage in the affected area
8. Active infection
9. Mental retardation
10. Psychiatric abnormality
11. Malignant disease
12. Patients with heart failure
13. Patients with pacemakers or implanted defibrillators
14. Patients with pulmonary congestion
15. Pregnancy

Date of first enrolment
01/12/2006

Date of final enrolment
01/07/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
VU Medical Centre
Amsterdam
Netherlands
1081 HV

Sponsor information

Organisation
Vrije University Medical Centre (VUMC) (The Netherlands)

Sponsor details
Department of Anesthesiology
P.O. Box 7057
Amsterdam
Netherlands
1007 MB

Sponsor type
Hospital/treatment centre

Website
http://www.vumc.nl/english/

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Government

Funder Name
SENTER - A branch of the Dutch Ministry of Economic Affairs (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2013	09/05/2019	Yes	No